

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

**BIOGEN INTERNATIONAL GMBH
and BIOGEN MA INC.,**

Plaintiffs,

v.

**AMNEAL PHARMACEUTICALS LLC,
et al.,**

Defendants.

**C.A. No. 17-823-MN
(Consolidated)**

**BIOGEN'S SUBMISSION REGARDING
NORTHERN DISTRICT OF WEST VIRGINIA JUDGMENT**

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INTRODUCTION

The Northern District of West Virginia’s ruling that the asserted claims of U.S. Patent 8,399,514 are invalid for lack of written description should not impact this Court’s determination in this action and does not require this Court to enter judgment for Defendants.¹

No motion for entry of judgment based on collateral estoppel has yet been filed, and this Court should not grant any such motion. Collateral estoppel is an equitable doctrine, and this Court has discretion to decline to apply the doctrine and reach its own judgment on the merits. *Blonder-Tongue Labs., Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 333-34 (1971) (“[The] decision [to apply collateral estoppel] will necessarily rest on the trial courts’ sense of justice and equity.”).² Given the advanced stage of these proceedings and the unusual circumstances that required Biogen to litigate in parallel in both West Virginia and Delaware, fairness and equity favor resolving all issues in this case on the merits, including the issue presented in both courts (written description) and the validity issues that were tried in this case but not addressed in West Virginia (anticipation, obviousness, enablement, improper inventorship, and derivation). This Court’s decision on the merits could then be reviewed on appeal alongside the West Virginia decision. The Federal Circuit would thus have the benefit of this Court’s rulings on the merits and could fully and finally resolve all pending challenges to the validity of the ’514 patent in a

¹ Biogen believes that the West Virginia case was wrongly decided and has appealed and moved for an injunction pending appeal under Fed. R. App. P. 8. *See Biogen Int’l GmbH v. Mylan Pharm. Inc.*, No. 2020-1933, Dkt. 14 (Fed. Cir. Jun. 29, 2020. On June 30, 2020, the Federal Circuit granted an interim injunction while it considers Biogen’s motion. *Id.*, Dkt. 22.

² *See also In re Freeman*, 30 F.3d 1459, 1467 (Fed. Cir. 1994) (“[A] court is not without some discretion to decide whether a particular case is appropriate for application of [issue preclusion].”); *JumpSport, Inc. v. Academy, Ltd.*, 2018 WL 4090471, at *7 (E.D. Tex. Aug. 28, 2018) (“[I]ssue preclusion ... is not without limitations. Issue preclusion is an equitable doctrine premised on principles of fairness.”); *SK Hynix, Inc. v. Rambus, Inc.*, 2013 WL 1915865, at *3 (N.D. Cal. May 8, 2013) (“[A]pplication of collateral estoppel is discretionary”).

timely manner, better serving the principles underlying collateral estoppel.

I. THE COURT SHOULD DECLINE TO APPLY COLLATERAL ESTOPPEL

This case presents an unusual example of two Hatch-Waxman cases involving generic challenges to the same patent proceeding to trial in two different district courts close in time. Biogen sought to defend against all generic challenges to the '514 patent in a single proceeding in this Court, but Mylan insisted on pursuing a parallel proceeding in West Virginia. Biogen diligently pursued the cases in both jurisdictions so that they could be resolved before the 30-month stay expires on September 27, 2020. The trial and post-trial briefing in this case are complete.

In these circumstances, Biogen believes the Court should exercise its discretion not to apply collateral estoppel. *See Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 692 F. Supp. 2d 487, 501-02 (M.D. Pa. 2010) (declining to apply collateral estoppel “in light of the unique circumstances presented” because trial was already completed and the Federal Circuit could resolve any inconsistencies on appeal). Two Hatch-Waxman cases involving generic challenges to the same patent have proceeded through trial on parallel tracks in two different districts close in time, with an appeal to the Federal Circuit by one side in both cases all but certain. Applying collateral estoppel in this unusual context would not serve the interests of judicial efficiency and fairness. *See JumpSport*, 2018 WL 4090471, at *9 (“A mechanical application of issue preclusion in the instant case would neither promote the underlying goals of issue preclusion (i.e., judicial economy and avoiding wasteful, unnecessary litigation), nor be consistent with principles of fairness and equity.”).

This case presents a very different situation from cases applying collateral estoppel where one proceeding lagged far behind the other and significant effort could be saved at the district

court level.³ Duplicative litigation has already occurred, as a result of Mylan's insistence on litigating in another district. *See Arlington Indus.*, 692 F. Supp. 2d at 502 (declining to apply collateral estoppel because "relitigation has already occurred"). Nor is it comparable to cases that have applied collateral estoppel based on an invalidity judgment by the *Federal Circuit* rather than by another district court.⁴

In fact, prematurely terminating this case based on collateral estoppel would have negative effects and could slow the ultimate resolution of the case. As noted, the issues in this case go beyond the sole question of written description addressed in West Virginia and include the issues of enablement, anticipation, obviousness, improper inventorship, and derivation. Issuing a ruling on the merits of the written description question, along with the other issues, would allow the Federal Circuit to review this Court's conclusions on all issues at the same time, at the end of which the parties would have likely achieved clarity on their respective rights. A ruling based on collateral estoppel could have the opposite effect, because if the Federal Circuit reverses the West Virginia decision on written description, it would need to remand this case for further proceedings. And the decision on remand would be subject to appeal, further delaying the final adjudication of this dispute.

This inefficiency would not be balanced by short-term conservation of judicial resources. If the Court were to apply collateral estoppel, Biogen would need to file a motion seeking to enjoin Defendants from launching their generic products pending appeal. The Court then would

³ *E.g., Galderma Labs., Inc. v. Amneal Pharm., LLC*, 921 F. Supp. 2d 278, 281, 283 (D. Del. 2012) (applying collateral estoppel where second case was still in fact discovery).

⁴ *E.g., Soverain Software LLC v. Victoria's Secret Direct Brand Mgmt., LLC*, 778 F.3d 1311, 1314 (Fed. Cir. 2015); *Pfizer, Inc. v. Synthon Holdings BV*, 227 F. App'x 903, 903 (Fed. Cir. 2007); *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1579-80 (Fed. Cir. 1994).

have to address the issue of written description in assessing the likelihood-of-success prong of Biogen's motion.

Biogen believes that the most fair and efficient course is for this Court to issue a decision on the merits and allow the two appeals to proceed to the Federal Circuit together. That would give the Federal Circuit the benefit of both district courts' opinions and provide the most efficient mechanism for resolving the dispute fully and finally.

The decision in *Arlington Industries* is instructive. There, the court found that a decision in another patent case would "otherwise be entitled to issue preclusive effect," but "decline[d] to apply the doctrine in light of the unique circumstances presented." 692 F. Supp. 2d at 501. The court explained that "[a]pplication of collateral estoppel is premised on fairness" and "is meant to foster judicial efficiency." *Id.* at 501-02 (internal quotation marks omitted). Applying collateral estoppel would not advance those ends, because the issue had already been "litigated before the [court] and a jury trial completed; in short, relitigation ha[d] already occurred." *Id.* at 502. In addition, "the Federal Circuit" could "resolve the inconsistent" rulings on appeal. *Id.* "Judicial economy and basic fairness" thus did not support application of collateral estoppel.

The *Arlington* court's decision not to apply collateral estoppel was ultimately vindicated: The Federal Circuit reversed the potentially preclusive judgment and summarily affirmed the *Arlington* court's determination on the merits. *Arlington Indus. Inc. v. Bridgeport Fittings, Inc.*, 477 Fed. App'x 740 (Fed. Cir. 2012). In fact, where a "considerable amount of time and expense has already been expended by the parties," the best course when confronted with a recent decision in another case that is still on appeal is to press forward to judgment, despite any inconsistency, and allow the Federal Circuit to proceed with the benefit of both courts' decisions.

See Jamesbury Corp. v. United States, 217 Ct. Cl. 658, 660 (1978).⁵

CONCLUSION

For the foregoing reasons, Biogen submits that this Court should deny any motion to enter judgment based on collateral estoppel. Instead, it should issue a decision on the merits.

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⁵ The Federal Circuit has adopted Court of Claims opinions as precedent. *Mendenhall*, 26 F.3d at 1579 n.6.